UNITED STATES COURT OF APPEALS
Tenth Circuit
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Denver, Colorado 80294
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June 10, 1997

TO: All recipients of the captioned opinion

RE: 95-1085, 95-1104, 95-1123, Oja v. Howmedica, Inc.
April 16, 1997

Please be advised of the following correction to the captioned decision:

Due to a formatting error, the section headings are incorrectly labeled. The Arabic numbers should be Roman numerals.

A corrected version of the opinion is attached for your convenience.

Very truly yours,

Patrick Fisher, Clerk

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F I L E D
United States Court of Appeals
Tenth Circuit

APR 16 1997

PATRICK FISHER
Clerk

PUBLISH

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

MAUREEN G. OJA,

Plaintiff - Appellee/
Cross - Appellant,

v.

HOWMEDICA, INC., a Delaware corporation,

Defendant - Appellant/
Cross - Appellee.

PRODUCT LIABILITY ADVISORY COUNCIL, INC.; HEALTH INDUSTRY MANUFACTURERS ASSOCIATION; ASSOCIATION OF TRIAL LAWYERS OF AMERICA,

Amici Curiae.

No. 95-1085, 95-1104, 95-1123

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
(D. Ct. No. 93-C-858)

Malcolm E. Wheeler, Parcel, Mauro, Hultin & Spaanstra, Denver, Colorado, appearing for Defendant-Appellant/Cross-Appellee.

Elizabeth C. Moran, Pryor, Johnson, Montoya, Carney & Karr, Englewood, Colorado (Peter W. Pryor, Pryor, Johnson, Montoya, Carney & Karr, Englewood, Colorado, and Thomas L. Roberts, Roberts & Zboyan, Denver, Colorado, with her on the briefs), appearing for Plaintiff-Appelle/Cross-Appellant.

Robert N. Weiner and Steve J. Boom, Arnold & Porter, Washington, DC, and Hugh Young, Jr., Product Liability Advisory Council, Inc., Reston, Virginia, for amicus curiae Product Liability Advisory Council, Inc.

Bruce N. Kuhlik and Jennifer A. Johnson, Covington & Burling, Washington, DC, and Donnellda Rice, Health Industry Manufacturers Association, Washington, DC, for amicus curiae Health Industry Manufacturers Association.

Pamela A. Liapakis, President, Association of Trial Lawyers of America, Washington, DC and Jeffrey Robert White, Washington, DC, for amicus curiae Association of Trial Lawyers of America.

Before TACHA, BRISCOE, and MURPHY, Circuit Judges.

TACHA, Circuit Judge.

Maureen Oja brought a products liability action against Howmedica, Inc., the manufacturer of a prothestic hip replacement system, asserting three claims relevant to this appeal: (1) negligence, (2) negligent failure to warn, and (3) strict liability. At the close of the plaintiff's case, the district court granted Howmedica's motion for a directed verdict on Oja's strict liability manufacturing defect claim. The court, however, permitted Oja to proceed with her strict liability claims based on design and warning defects.

The jury returned a general verdict for Howmedica on the negligence and remaining strict liability claims. The jury, however, found for Oja on her negligent failure to warn claim. The jury awarded Oja $896,921 in compensatory and $896,921 in punitive damages. The district court reduced the damage award to $448,460.50 and $612,535.96, respectively, and awarded Oja prejudgment interest from the date the action accrued.

On appeal, Howmedica argues that: (1) the Medical Device Amendments of 1976 ("MDA") preempts Oja's negligent failure to warn claim; (2) the jury's finding of negligent failure to warn is inconsistent with its verdict for Howmedica on the strict liability and negligence claims; (3) the district court erred in submitting both a "negligence" and "negligent failure to warn" claim to the jury without properly instructing the jury about the elements and burdens of proof on each claim; and (4) punitive damages cannot be awarded as a matter of law because the evidence was insufficient to show that Howmedica acted wantonly or recklessly.

In her cross-appeal, Oja raises two issues. Oja argues that the district court erred in (1) dismissing her strict liability claim based on a manufacturing defect and (2) awarding her prejudgment interest from the date that her action "accrued" as defined by the relevant statute of limitations rather than the date of her injury.

We exercise jurisdiction pursuant to 28 U.S.C. § 1291. For the reasons set forth below, we affirm the district court's ruling that the MDA does not preempt Oja's negligent failure to warn claim. We reverse and remand for a new trial, however, because we conclude that the jury's finding of negligent failure to warn is irreconcilably inconsistent with its verdict for Howmedica on the strict liability claim. We also reverse the district court's order granting a directed verdict for Howmedica on the strict liability manufacturing defect claim. Because we remand for a new trial, we do not address the remaining issues on appeal.

BACKGROUND

The Porous-Coated Anatomic One-Piece Acetabular Component hip ("PCA hip") consists of three components: (1) a metal stem that is inserted into the central canal of the patient's large upper leg bone, (2) a cup that is inserted into the patient's hip socket, and (3) a rounded metal femoral head that is rigidly attached to the top of the metal stem and is fitted into the cup. The cup is composed of an outer metal shell and an inner polyethylene liner. The liner attaches to the metal shell by an integral staking peg projecting from the back of the liner through a hole in the metal shell. An "anti-rotation lug" prevents the liner from rotating in the metal shell. Unless the liner is prevented from rotating,

the liner will wear and shed microscopic debris. Such debris may cause a patient to suffer from severe bone dissolution or "osteolysis."

On July 2, 1984, Oja underwent surgery to replace her existing artificial hip with a PCA hip. Her orthopedic surgeon, Dr. McElhinney, implanted the PCA hip without using cement because he had concluded that Oja's existing bone structure provided little area for cement fixation.

By early 1992, Oja began experiencing severe pain in her hip in the area of her PCA hip implant. Dr. Richard Evans, an orthopedic surgeon, recommended immediate surgery. On July 29, 1992, he removed the PCA hip. The surgery revealed that the staking peg was missing, that the polyethylene liner had completely disengaged from the metal cup, and that debris had spread into Oja's hip joint. Moreover, osteolysis had left large defects in Oja's hip, especially in the area of the hole in the cup. On April 21, 1993, Oja filed this products liability suit against Howmedica.

DISCUSSION

I. PREEMPTION OF OJA'S NEGLIGENT FAILURE TO WARN CLAIM

a. Overview of the Medical Device Amendments

Howmedica argues that the MDA preempts Oja's negligent failure to warn claim.[1] Because Congress's intent is the "ultimate touchstone" in every preemption case, see Retail Clerks Int'l Ass'n v. Schermerhorn, 375 U.S. 96, 103 (1963), we begin our preemption analysis by outlining the purposes and statutory framework of the MDA.

In 1976, Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." Pub. L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). The MDA classifies medical devices into three categories (classes I, II and III) based on the amount of risk they pose to the public. Class I devices are subject only to "general controls" because they pose little threat to public heath and safety. 21 U.S.C. § 360c(a)(1)(A). Class II devices are subject to special controls because "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of

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[1]Prior to trial, Howmedica moved for summary judgment, claiming that all of Oja's state law claims were preempted by the MDA. The district court denied Howmedica's motion and its motion for reconsideration. At the close of the evidence, Howmedica moved for a directed verdict on all of Oja's state law claims based on MDA preemption. The district court denied the motion.

After the jury returned its verdict, Howmedica renewed its motion for judgment as a matter of law, arguing only that the MDA preempted Oja's negligent failure to warn claim. The district court denied the motion. On appeal, Howmedica again argues only that the MDA preempts Oja's negligent failure to warn claim. Thus, we do not address whether the MDA preempts any of Oja's other state law claims. See State Farm Fire & Cas. Co. v. Mhoon, 31 F.3d 979, 984 n.7 (10th Cir. 1994) (holding that the failure to raise an issue in the opening brief waives the issue).

the device." 21 U.S.C. § 360c(a)(1)(B). Class III devices are subject to the most stringent MDA controls because they present "a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C).

The MDA automatically classifies a device as a class III device unless the device fits within one of three exceptions listed. First, a device placed in commercial distribution prior to May 28, 1976, avoids class III status through a grandfathering provision. 21 U.S.C. § 360c(f)(1)(A)(I)(I). Second, a post-1976 device may escape classification as a class III device if the FDA has reclassified the device as a class I or II device. 21 U.S.C. § 360c(f)(1)(A)(I)(II); 21 U.S.C. § 360c(f)(1)(B). Finally, a device may avoid class III device status if it is "substantially equivalent" to a grandfathered device or a post-1976 device that the FDA has classified as a class I or II device. 21 U.S.C. § 360c(f)(1)(A)(ii).

Manufacturers intending to market any new medical device must submit a premarket notification to the FDA. 21 U.S.C. § 360(k). In addition to the premarket notification (also known as the "§ 510(k) process"), Class III devices must undergo a comprehensive premarket approval ("PMA") process before marketing. 21 U.S.C. § 360e. The purpose of the PMA is to provide the FDA with "reasonable assurance" that the device is safe and effective. 21 U.S.C. § 360e(d)(2).

While the MDA contemplates that most Class III devices will reach the market only through the PMA process, a manufacturer may obtain market approval through any of three alternative processes. First, the MDA contains a grandfathering provision which allows pre-1976 devices to remain on the market without FDA approval until the FDA completes the PMA. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1). Second, the MDA contains an investigational device exemption ("IDE") for new devices under clinical investigation to determine their safety or effectiveness. See 21 U.S.C. § 360j(g). In order to foster the development of useful devices, IDE procedures allow manufacturers to begin limited marketing of new devices without undergoing the rigorous PMA process. 21 U.S.C. § 360j(g)(1). Finally, a Class III device may reach the market without undergoing the PMA procedures if the FDA determines, on the basis of the § 510 process, that the device is "substantially equivalent" to a device already on the market. 21 U.S.C. § 360e(b)(1)(B).

b. Regulation of the PCA Hip Under the MDA

On April 25, 1983, Howmedica filed a premarket notification submission with the FDA, seeking permission to market the PCA hip under the § 510(k) process. The application included sample labels, a description of the intended use, a description of the product (dimensions, materials, processing, and sterilization procedures), photographs of the components, engineering drawings,

and a description of test results. During the next few months, the FDA requested that Howmedica submit additional testing information and certification that the PCA hip would be used only with cement. Howmedica complied with each of these requests.

On August 10, 1983, the FDA granted Howmedica permission to market the PCA hip for use with bone cement pursuant to the § 510(k) process "subject to the general controls provision of the Federal Food, Drug & Cosmetic Act." The FDA also imposed several specific limitations on Howmedica: (1) the PCA hip could not be labeled or promoted for non-cemented use, (2) the PCA hip could only be used with low-viscosity cement, and (3) fixation of the PCA hip without cement would be considered an investigational procedure requiring an IDE.

On October 18, 1983, Howmedica submitted an IDE application in order to conduct a clinical study of the PCA hip when used without cement.[2] Over the course of the next year, Howmedica submitted animal studies, comparative control groups, and other information to the FDA. On December 12, 1984, the FDA authorized Howmedica to conduct the clinical investigation. After that date,

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[2]Oja underwent her PCA hip surgery on July 2, 1984, when Howmedica's IDE application was pending. Thus, at the time of Oja's surgery, Howmedica had not yet received an IDE for cementless use. This distinguishes our case from Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997) and Becker v. Richards Med. Co., 937 F. Supp. 181 (N.D.N.Y. 1996).

the PCA could be used without cement in an experimental context, with a patient's full informed consent.

On September 4, 1987, the FDA issued its final rule classifying the PCA hip as a class II medical device when used with cement. 52 Fed. Reg. 33686, 33707 (codified at 21 C.F.R. § 888.350). At that time, the FDA had determined that classification as a class III device was "not necessary to provide reasonable assurance of the safety and effectiveness of the device." 21 C.F.R. § 860.93.

On October 26, 1989, following the clinical investigation of the PCA hip, Howmedica filed a request for a PMA to market the PCA hip when used without cement. The FDA issued a conditional approval letter on April 2, 1991. The FDA conditioned final approval upon: (1) deleting one word from the proposed labeling, (2) providing an update of the clinical database, and (3) complying with future requirements, such as the summation of long-term survivorship data.

In 1991, the FDA inspected and cited Howmedica for several regulatory violations, including the failure to report information that the PCA hip had caused serious injury in patients. In response, Howmedica informed the FDA that it would "voluntarily" issue a "Dear Doctor" letter to surgeons using the device, instructing them on the proper surgical techniques to avoid damage to the polyethylene liner of the cup. The FDA indicated that it had "no adverse comments" about the content of the letter.

On February 21, 1992, the FDA reclassified the PCA hip when used without cement from a class III device to a class II device. See 58 Fed. Reg. 3227 (Jan. 8, 1993). Howmedica therefore invoked the § 510(k) process (rather than the more rigorous PMA) to obtain authorization to market the PCA hip without cement. On June 10, 1992, the FDA granted Howmedica permission to market the PCA hip when used without cement under the premarket notification procedure. On January 8, 1993, the FDA published its final rule classifying the PCA hip as a class II medical device when used without cement. 58 Fed. Reg. 3227, 3228 (codified at 21 C.F.R. § 888.358)

c. MDA Preemption Analysis in *Medtronic, Inc. v. Lohr*

In Medtronic, Inc. v. Lohr, 116 S. Ct. 2240 (1996), the Supreme Court addressed whether the MDA's general labeling regulations preempted a state law negligent failure to warn claim for injuries suffered by the recipient of a pacemaker, a class III device.[3] Id. at 2256-58. The regulations require manufacturers of every medical device, with a few limited exceptions, to label the device with "information for use, . . . any relevant hazards, contraindications, side effects, and precautions." 21 C.F.R. § 801.109(c).

[3]In a five to four decision, the Court held that the MDA did not preempt any of the plaintiffs' common law claims. Justice Stevens authored the plurality opinion, which Justices Kennedy, Souter, and Ginsburg joined in its entirety. Justice Breyer, who concurred in the judgment, joined in Parts I, II, III, V, and VII of the plurality opinion. Thus, only those five sections constitute the opinion of the Court.

The Court began its preemption analysis by looking to the text of the MDA's preemption provision (21 U.S.C. § 360k) and the FDA's regulation interpreting that provision (21 C.F.R. § 808.1(d)):

> § 360k State and local requirements respecting devices
> (a) General Rule
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> § 808.1 Scope
> (d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act, thereby making any existing divergent state or local requirements applicable to the device different from or in addition to, the specific Food and Drug Administration requirements.

Medtronic, 116 S. Ct. at 2256-58. The Court concluded that the statute and regulation evinced "an overarching concern that pre-emption occurs only where a particular state requirement threatens to interfere with a particular federal interest." Id. at 2257.

Based on the MDA's statutory language and the FDA's regulation, the Court developed a two-prong inquiry to determine the preemptive scope of the MDA. Id. First, a federal requirement must be "applicable to the device" in

question. Id. at 2257 (quoting 21 U.S.C. § 360k). In other words, a federal requirement will preempt state law only if "specific" to a "particular device." Id. (quoting 21 C.F.R. § 808.1(d)). Second, a state requirement must be "with respect to" a medical device and must be "different from, or in addition to" a federal requirement. Id. (quoting 21 U.S.C. § 360k). Accordingly, "[s]tate regulations of 'general applicability' are not preempted except where they have 'the effect of establishing a substantive requirement of a specific device.'" Id. (quoting 21 C.F.R. § 808.1(d)(1)).

Applying the two-prong test, the Court concluded that the MDA's labeling regulations did not preempt the plaintiffs' negligent failure to warn claim. First, the Court found no preemption because the federal labeling regulations reflected "important but entirely generic concerns about device regulation generally." Id. at 2558. Second, the Court concluded that the negligent failure to warn claim also escaped preemption because its "generality leaves [it] outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices." Id.

d. Application of *Medtronic*

In its supplemental brief, Howmedica argues that the FDA imposed two warning requirements sufficient to preempt Oja's negligent failure to warn claim.[4]

[4]Prior to the Supreme Court's decision in Medtronic, Howmedica argued that several FDA "requirements" would preempt Oja's negligent failure to warn claim. The Supreme Court rejected most of these grounds in Medtronic. Accordingly, in

Howmedica points to the FDA's regulation of the PCA hip in 1983 and in 1991. With respect to Howmedica's dealings with the FDA in 1983, Howmedica alleges:

> In 1983, when first deciding whether to allow Howmedica to begin marketing the PCA hip, the FDA four times required Howmedica to submit more testing, information, and certifications . . . and then required Howmedica to add, to all labeling and promotional materials for that specific device, specific warning statements that the device be used only with bone cement, not cementless . . . . The warnings specifically required by the FDA did not include any of the warnings that Oja asked the jury to impose under Colorado tort law.

Applt. Supp. Brief at 4 (citations omitted).

Under the Medtronic two-pronged preemption test, we must first determine whether the FDA imposed any specific federal warning requirement applicable to the PCA hip in its 1983 dealings with Howmedica. The record indicates that the FDA imposed only one labeling requirement on Howmedica: the FDA stated that Howmedica could not label or promote the PCA hip for non-cemented use. This mandate constitutes a specific federal requirement applicable to the PCA hip, but that does not end our preemption inquiry. Like the failure to warn claim at issue in Medtronic, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Medtronic, 116. S. Ct. at 2258. Instead, Oja's negligent failure

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Howmedica's supplemental brief filed after Medtronic, Howmedica limited its preemption argument to the only viable grounds remaining, namely the FDA's dealings with Howmedica in 1983 and 1991. Thus, we address only these grounds.

to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use." Id. Moreover, Howmedica's general duty to warn users of potential dangers in this case does not have "the effect of establishing a substantive requirement for a specific device." Id. at 2257. Thus, the standard of care governing Oja's negligent failure to warn claim is not the type of device-specific requirement that would threaten the MDA's federal interests. See id. at 2258. Accordingly, we find no preemption based on Howmedica's dealings with the FDA in 1983.

Similarly, we find no preemption based on the FDA's regulation of the PCA hip in 1991. Howmedica alleges:

> In 1991 the FDA specifically scrutinized Howmedica's internal documents regarding reported problems with the PCA hip, reexamined Howmedica's medical device reports pertaining to the PCA hip (including reports relied on by Oja at trial as evidence of the need for additional warnings), reexamined Howmedica's labeling and warning materials, and imposed device-specific requirements for specific additional labeling and warnings. The warnings required by the FDA did not include any of the warnings that Oja asked the jury to require under Colorado tort law. . . .

Applt. Supp. Brief at 3-4 (citations omitted). First, we note that any FDA requirement imposed in 1991 would have no preemptive effect as to Howmedica's pre-1991 post-sale duty to warn. Second, the record is not clear that the 1991 "voluntary" Dear Doctor letter even constituted an MDA "requirement" at all.

We need not resolve this question, however, because assuming arguendo that the warnings contained in the letter were specific federal requirements, we find no preemption under the second prong of the analysis employed in Medtronic. As with the 1983 claims, the duties imposed by Oja's negligent failure to warn claim do not constitute positive enactments of state law sufficient to constitute a state requirement developed "with respect to" a medical device. The Court in Medtronic made clear that the general duty to warn of foreseeable dangers is "not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." Medtronic, 116 S. Ct. at 2258. Accordingly, we affirm the district court's ruling that the MDA does not preempt Oja's negligent failure to warn claim.

II. INCONSISTENT JURY VERDICTS

a. Waiver

Howmedica next contends that we should vacate the judgment entered on the jury verdict in favor of Oja on her negligent failure to warn claim because it is irreconcilably inconsistent with the jury verdict in favor of Howmedica on Oja's strict liability claims. As a preliminary matter, we must determine whether we may review this issue. A party's failure to object to a general jury verdict on the ground of inconsistency before the jury is discharged constitutes waiver, unless

the verdict is inconsistent on its face such that entry of judgment upon the verdict is plain error. Hinds v. General Motors Corp., 988 F.2d 1039, 1047 (10th Cir. 1993) (citing Diamond Shamrock Corp. v. Zinke & Trumbo, Ltd., 791 F.2d 1416, 1424 (10th Cir. 1986)).

In this case, the parties do not dispute that the verdict forms required the jury to return a general verdict. The jury reached a verdict at 5:00 pm on the night before Thanksgiving. The court then read the verdict, polled the jury, entered judgment, and excused the jurors. Howmedica relies on Jarvis v. Commercial Union Assurance Cos., 823 F.2d 392, 393 (10th Cir. 1987), to support its position that under these circumstances, Howmedica had no "meaningful opportunity" to object to the verdict and therefore its failure to object should not constitute waiver. In Jarvis, the jury returned a verdict and special interrogatory answers that the trial judge recognized as arguably inconsistent. Id. at 394. In open court, the judge asked the jury to review its verdict and answers to determine if the jury marked the forms as intended. Id. After further deliberations, the jury sent the judge a note stating that the forms were correctly marked and that "if there is a conflict with the Special Interrogatory form and the Verdict Forms, we will need a description of this conflict." Id. at 395. The court informed the parties of the jury's note and explained:

> I wanted to inquire if there was an inconsistency in the jury's mind. They are saying that there is none, so I am going to bring them in and publish the verdict.

Id. at 394. Accordingly, the judge read the verdict, polled the jury, entered judgment, and discharged the jury. Id. We held that "it would be a perverse default of justice to say that under the circumstances present here, counsel had waived the right to correct an onerous inconsistency in the jury's resolution of his client's case only because he did not raise an objection." Id. at 396.

We find Howmedica's reliance on Jarvis misplaced. In Jarvis, "the court summarily declared the conflict resolved and proceeded with entry of the verdict." Id. Under such circumstances, an objection to the verdict as inconsistent would have been frivolous in light of the trial court's disposition of the issue. In contrast to Jarvis, the trial court in this case did not raise and decide the issue sua sponte before discharging the jury. Instead, the record indicates that Howmedica had the opportunity to object to any inconsistencies in the verdict prior to the jury's discharge or immediately thereafter. In fact, Howmedica's counsel objected to at least one aspect of the verdict before leaving the courtroom. The attorney stated: "I think there are some problems with the verdict in that there are -- seems to me the punitive damages are above the compensatory." Howmedica could have made similar objection to the verdict being inconsistent or complained that the trial court discharged the jury before Howmedica could make such an

objection. Howmedica did not do this. Under such circumstances, we hold that Howmedica has waived its right to object to the verdict unless it is "inconsistent on its face such that entry of judgment upon the verdict is plain error." Hinds, 988 F.2d at 1047.

b. Facial Inconsistency

"A verdict that resolves separate and distinct causes of action in favor of both parties is not inconsistent on its face." Harris Mkt. Research v. Marshall Mktg. & Communications, Inc., 948 F.2d 1518, 1522 (10th Cir. 1991). In contrast, when "several causes of action are identical and defended on the same ground, a verdict for the plaintiff on one cause of action and for the defendant on another is inconsistent." Diamond Shamrock Corp., 791 F.2d at 1425.

To determine whether the verdicts in this case are irreconcilably inconsistent, we must examine the relationship between strict liability and negligence under Colorado law. In Fibreboard Corp. v. Fenton, 845 P.2d 1168, 1174 (Colo. 1993) (en banc), the Supreme Court of Colorado stated:

> Under a negligence theory a plaintiff is required to prove that a manufacturer's failure to warn of a risk fell below an acceptable standard of care. Under a strict liability theory, however, the focus of the inquiry is whether the defendant failed to warn of particular risks that were known or knowable in light of the generally recognized and prevailing scientific and technical knowledge available at the time of manufacture and distribution.

Despite the theoretical differences noted in Fibreboard Corp., we have recognized that Colorado has not drawn a "rigid distinction between negligence and strict liability failure to warn concepts." Romero v. International Harvester Co., 979 F.2d 1444, 1452 (10th Cir. 1992). For example, as with all tort claims, the plaintiff must prove the elements of causation and damages. More importantly, "[o]ne critical area of overlap is that, '[r]egardless of whether a product liability action is grounded in negligence or strict liability, a plaintiff must prove that the product was defective.'" Perlmutter v. United States Gypsum Co., 54 F.3d 659, 663 (10th Cir. 1995) (quoting Mile High Concrete, Inc. v. Matz, 842 P.2d 198, 205 (Colo. 1992)). Under either theory, the product must have been defective at the time of sale. See Perlmutter v. United States Gypsum Co., 4 F.3d 864, 869 (10th Cir. 1993) (holding that in a negligence claim, there is "no post-sale duty to warn or remedy when the product was non-defective under standards existing at the time of manufacture"); Fibreboard Corp., 845 P.2d at 1175 (stating that "[i]n [strict liability] failure-to-warn cases, a product is not defective and unreasonably dangerous if a particular risk is not known or knowable in light of the generally recognized and prevailing scientific and technical knowledge available at the time of manufacture and distribution").

In this case, the elements of defectiveness and causation were common to all of Oja's claims. The record on appeal reveals that these two elements were

essentially the only elements disputed at trial. To find for Oja on her negligent failure to warn claim, the jury had to find that the PCA hip was defective at the time of sale and caused her injuries.[5] To find for Howmedica on Oja's strict liability claim, the jury had to find that the PCA hip was either not defective at

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[5]The jury instruction regarding Oja's negligent failure to warn claim stated:

> If a product manufacturer knows, or in the exercise of reasonable care should know, that use of the product may be harmful or injurious to a user, and such risk of harm or injury is not obvious to a reasonable surgeon, then the manufacturer must use reasonable care to warn the surgeon of the risk of harm or injury if, and to the extent, and in the manner, a reasonably careful person would warn under the same or similar circumstances.
>
> The duty to warn may extend beyond the time of sale of a product where a danger concerning the product becomes known to the manufacturer subsequent to the sale and delivery of the product, even though it was not known at the time of the sale. A manufacturer has no duty to warn surgeons regarding its product after the product is sold unless you find that the product was defective and unreasonably dangerous as originally designed and sold. Where dangerous defects in design come to the manufacturer's attention after the device has been sold, the manufacturer has a duty to either remedy such defects, or, if such a complete remedy is not feasible, to give physicians adequate warnings and instructions concerning methods for minimizing danger and injury. Failure to do so is negligence.
>
> A manufacturer has no duty to warn surgeons using a product about a newly developed safety device if the product was not defective under standards existing at the time the product was manufactured.
>
> Whether or not the PCA hip was defective as originally sold should be determined by the standard set forth in these instructions of the plaintiff's claim for sale of a defective product.
>
> Here, too, if the defendant had a duty to warn, it would be a duty to warn members of the medical profession, including the plaintiff's surgeons.

the time of sale or did not cause her injuries.[6] Given these parameters, we hold that the verdict for Oja on her negligent failure to warn claim and the verdict for Howmedica on Oja's strict liability failure to warn claim were facially inconsistent. Accordingly, we vacate the judgment of the district court and order a new trial.

III. DIRECTED VERDICT ON THE MANUFACTURING DEFECT CLAIM

In her cross-appeal, Oja argues that the district court erred in directing a verdict for Howmedica on Oja's manufacturing defect claim. The district court concluded that Oja had failed to present any evidence to support a jury finding that the PCA hip contained a manufacturing defect. Instead, the court found that Oja had presented evidence sufficient only to permit a jury to find that the PCA hip suffered from a design defect.

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[6]With respect to the strict liability for failure to warn claim, the jury instructions stated in relevant part:

> For the plaintiff, Ms. Oja, to recover from the defendant, Howmedica, on her claim for sale of a defective product, you must find that all of the following facts have been proved by a preponderance of the evidence:
> (1) The PCA hip was defective and, because of one or more defects, it was unreasonably dangerous to a person who might reasonably be expected to use it or be affected by it;
> (2) The PCA hip was defective at the time it was sold by the defendant or left its control;
> (3) Plaintiff incurred injuries, damages or losses; and
> (4) The defect in the PCA hip was a cause of the plaintiff's injuries, damages or losses.

We review the district court's grant of a directed verdict de novo, applying the same standard used by the district court. Knight v. Snap-on Tools Corp., 3 F.3d 1398, 1401 (10th Cir. 1993). "A directed verdict is appropriate only if the evidence, viewed in the light most favorable to the nonmoving party, 'points but one way and is susceptible to no reasonable inferences supporting' the nonmoving party." Id. (internal citations omitted). "However, a mere scintilla of evidence is insufficient to create a jury question." Honce v. Vigil, 1 F.3d 1085, 1088 (10th Cir. 1993). Although federal law dictates whether a directed verdict is appropriate, in a diversity action we examine the evidence in terms of the underlying burden of proof as dictated by state law. Mason v. Texaco, Inc., 948 F.2d 1546, 1554 (10th Cir. 1991).

In Hiigel v. General Motors Corp., 544 P.2d 983, 988 (Colo. 1975), the Supreme Court of Colorado expressly adopted the doctrine of strict liability in tort for selling a product in a "defective condition unreasonably dangerous to the user or consumer" as stated in section 402A of the Restatement (Second) of Torts. To avoid a directed verdict in a strict liability action brought under Colorado law, a plaintiff must offer proof of each element set forth in section 402A sufficient to create an issue of fact. Belle Bonfils Mem'l Blood Bank v. Hansen, 665 P.2d 118, 125 n.12 (Colo. 1983). In particular, a plaintiff must offer sufficient evidence that the product at issue was in a "defective condition unreasonably

dangerous" at the time the product was sold to the plaintiff. White v. Caterpillar, Inc., 867 P.2d 100, 104-05 (Colo. Ct. App. 1993). A claim of defect can be premised on a manufacturing, design, or warning defect. Id. at 105. "The question in manufacturing defect cases is whether the product as produced conformed with the manufacturer's specifications." Camacho v. Honda Motor Co., 741 P.2d 1240,1247 (Colo. 1987). A defect in manufacturing usually occurs because of insufficient quality control. See, e.g., LEWIS BASS, PRODUCTS LIABILITY: DESIGN AND MANUFACTURING DEFECTS, § 4.07, at 57 (1986).

Under Colorado law, a plaintiff may prove a manufacturing defect by direct or circumstantial evidence. See Union Ins. Co. v. RCA Corp., 724 P.2d 80, 82-83 (Colo. Ct. App. 1986). In this case, the staking peg was completely missing when Dr. Evans removed Oja's PCA hip. Under such conditions, direct proof of a defect in the staking peg was impossible. See id. at 83. Accordingly, Oja relied exclusively on circumstantial evidence to support her manufacturing defect claim.

Oja's surgeon testified that he made only a visual check for improper staking before implanting the PCA hip. Her expert concluded that although the surgeon saw no noticeable defect in the device, the PCA hip could still have suffered from an internal manufacturing defect in the staking peg. To support her claim, Oja introduced evidence that Howmedica received at least two product experience reports ("PERs") describing instances in which surgeons discovered a

staking problem only after implanting the PCA hip and performing a trial reduction.

In addition to those two PERs, Oja submitted six other PERs describing inadequate staking in PCA hips manufactured near the time Howmedica manufactured Oja's PCA hip. In particular, Howmedica received a PER on February 1, 1984, that stated:

> **Nature of Complaint [By Surgeon]:** Please replace to my stock--no charge--while dislocating the hip during a trial reduction in surgery the plastic core came out of metal backing.
>
> **Results of Evaluation [By Howmedica Employee]:** The assembly staking on above part was inadequate. We have established a push test & careful visual inspection (100%) on PCA acetabular cup assemblies which should preclude such failures.

Similarly, Howmedica received a PER on August 27, 1984, that stated:

> **Nature of Complaint [By Surgeon]:** Customer complains that the HDP is not close enough in the metal part.
>
> **Results of Evaluation [By Howmedica Employee]:** As received the fit of the insert to the cup was excellent but the stake holding the components together was poor. This part was of very early production (Oct. 1983) and the staking process still required improvement. The process has been improved and we have also added a "push test" to the stake to assure adequate assembly.

Finally, Oja submitted evidence indicating that Howmedica rejected one of the PCA hips from the same lot as Oja's PCA hip because of a staking problem. The remaining devices in her lot underwent a "tightness of plastic insert to cup VISUAL" test. Howmedica did not, however, conduct any other performance

tests on the lot of PCA hips containing her hip. Oja claims the absence of adequate inspection and testing procedures increased the likelihood that her PCA hip suffered from a manufacturing defect.

We have carefully reviewed the record and conclude that Oja presented sufficient evidence from which a jury could reasonably conclude that Oja's PCA hip suffered from a manufacturing defect. The staking peg in Oja's PCA hip was completely missing. Within a year of the device's manufacture, Howmedica sent a number of other PCA hips to surgeons that did not "conform to [Howmedica's] specifications" because of inadequate staking. See Camacho, 741 P.2d at 1247. The PERs strongly suggest that problems with inadequate staking were not infrequent during early production of the PCA hip. More importantly, the PERs indicate that the problems could have been caused by inadequate testing and inspection in the manufacturing process, in addition to inadequate design. Under such circumstances, we hold that a jury could reasonably conclude that Oja's PCA hip suffered from a manufacturing defect.

CONCLUSION

We AFFIRM the district court's order finding that the MDA does not preempt Oja's negligent failure to warn claim. We VACATE the judgment entered on the jury's verdict and REMAND for a new trial because we hold that

the jury's verdict for Howmedica on the strict liability failure to warn claim but against Howmedica on the negligent failure to warn claim are irreconcilably inconsistent. We also REVERSE the directed verdict for Howmedica on Oja's strict liability manufacturing defect claim. Because we remand for a new trial, we do not address the remaining issues presented on appeal.